

**Department of State Health Services
Council Agenda Memo for State Health Services Council
June 14, 2012**

Agenda Item Title: New rule concerning Autologous Adult Stem Cell Banks

Agenda Number: 4.a

Recommended Council Action:

☐ For Discussion Only

☒ For Discussion and Action by the Council

Background:

The Office of General Counsel (OGC) is located within the Chief Operating Officer Division. The purpose of OGC is to provide legal support and counsel to all DSHS programs and facilities statewide. The OGC program budget and source of funding is general revenue. OGC is promulgating this rule because the rule is non-regulatory and does not fit under a specific DSHS program but requires input from more than one program. This rule will not incur costs to OGC or any other DSHS program.

Summary:

The purpose of the proposed new rule is to implement Senate Bill 7, Article 14, 82nd Legislature, First Called Session, 2011, which added new Health and Safety Code (HSC), Chapter 1003. HSC, Section 1003.001(a) requires the Executive Commissioner of the Health and Human Services Commission to establish eligibility criteria by rule for the creation and operation of autologous adult stem cell banks, if the Executive Commissioner determines that it will be cost-effective and will increase the efficiency or quality of health care, health and human services, and health benefits programs in this state to do so. The Executive Commissioner and DSHS have determined the cost-effectiveness and efficiency of the implementation of HSC, Chapter 1003, and DSHS proposes Section 1.451 to implement HSC, Section 1003.001.

Operators of autologous adult stem cell banks will be impacted by the rule, as well as persons who store adult stem cells in the banks for autologous transfusions.

Key Health Measures:

The proposed new rule is expected to provide criteria to establish and operate autologous adult stem cell banks. Currently, no such specific criteria exist for autologous adult stem cell banks, and DSHS expects the rule to assist in ensuring the safety and efficiency of the adult stem cell banks. This should protect the persons who store and use adult stem cells and the adult stem cells stored in the adult stem cell banks. DSHS does not anticipate any negative unintended consequences to arise from this rule. Because the statute and proposed rule does not require DSHS to enforce or regulate autologous stem cell facilities, DSHS will rely on continued stakeholder input for outcome measures of the rule impact.

Summary of Input from Stakeholder Groups:

DSHS held a stakeholder meeting on February 21, 2012, to gather information about the definition, creation, and operation of autologous adult stem cell banks. Attending were representatives of the following: Texans for Stem Cell Research; Arnold Public Affairs; University of Texas; Texas Alliance for Life; Celltex; South Texas Blood and

Tissue Center; Texas Medical Board; the Texas Legislature; Office of the Governor; Health and Human Services Commission; and Texas Star Alliance. Also attending were representatives from the DSHS Division for Regulatory Services; Laboratory Services Section; Office of General Counsel; Center for Consumer and External Affairs; State Health Services Council; and Commissioner's Office.

The stakeholders present at the February 21, 2012, stakeholder meeting provided input concerning the following questions:

- The definition of an adult stem cell bank, how such an entity is established, maintained, and operated, and what services are provided.
- The qualifications of an entity that would operate such a facility.
- Existing criteria or best practices that DSHS could review in order to better understand the answers to the first two questions.

Responses from the group to the questions were recorded on flipcharts. The rule was drafted after the stakeholder input meeting, incorporating the input received. The proposed rule will be sent to stakeholders representing adult stem cell bank operators; other blood and tissue banks; professional associations; medical schools; schools of public health and other universities; and other groups involved in adult stem cell research and treatment. In addition, members of the public will be able to comment during the 30-day *Texas Register* publication comment period.

Proposed Motion:

Motion to recommend HHSC approval for publication of rule contained in agenda item #4.a.

Approved by Assistant Commissioner/Director:		Marc Connelly	Date:	5/9/12
Presenter:	Kirk Cole	Program:	Associate Commissioner	Phone No.: 512-776-7376
Approved by CCEA:		Carolyn Bivens	Date:	5/9/12

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 1. Miscellaneous Provisions
Subchapter V. Autologous Adult Stem Cell Banks.
New §1.451

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes new §1.451, concerning criteria for establishing and operating autologous adult stem cell banks.

BACKGROUND AND PURPOSE

This new subchapter will implement Senate Bill 7, Article 14, 82nd Legislature, First Called Session, 2011, which added new Health and Safety Code, Chapter 1003, (regarding Autologous Stem Cell Bank for Recipients of Blood and Tissue Components Who Are the Live Human Donors of the Adult Stem Cells). Health and Safety Code, Chapter 1003 requires the Executive Commissioner of the Health and Human Services Commission to establish by rule eligibility criteria for the creation and operation of an autologous adult stem cell bank, if the Executive Commissioner determines that it will be cost-effective and will increase the efficiency or quality of health care, health and human services, and health benefits programs in this state to do so. The Executive Commissioner and the department have determined the cost-effectiveness and efficiency of the implementation of Health and Safety Code, Chapter 1003.

This new rule applies to autologous adult stem cell bank operators. The department obtained input concerning the definition, creation, and operation of autologous adult stem cell banks from outside stakeholders and department stakeholders. Specifically, a February 21, 2012, stakeholder meeting was attended by representatives from Texans for Stem Cell Research, Arnold Public Affairs, the University of Texas, Texas Alliance for Life, Celltex, the Texas Medical Board, the Texas Legislature, the South Texas Blood and Tissue Center, the Office of the Governor, one member of the State Health Services Council, the Health and Human Services Commission, and Texas Star Alliance. The department's Division for Regulatory Services and the Laboratory Services Section provided input in drafting this rule. The department will be sending the proposed rule to adult stem cell bank operators; blood and tissue banks; professional associations; medical schools, schools of public health, and other universities; and other groups involved in adult stem cell research and treatment. Other stakeholders will have an opportunity to comment on the proposed rule during the 30-day rule publication comment period.

SECTION-BY-SECTION SUMMARY

New §1.451 implements Health and Safety Code, Title 12, Chapter 1003, by setting out establishment and operation criteria for autologous adult stem cell banks in Texas. The guidelines for autologous adult stem cell banks require a governing body, which is responsible for facility organization, management, control, staffing, and operation. The governing body must be formally organized with written bylaws and a constitution and is responsible for

adoption, implementation, and enforcement of facility policies and procedures. Autologous adult stem cell banks also must use current scientific standards; ensure that services are provided safely and effectively complying with all state and federal laws and regulations; and adopt and implement an ongoing quality assessment and performance improvement program. An autologous adult stem cell bank must file certain information with the department. The information is not an endorsement by the department and may not be used in advertising by the stem cell bank, its parent or agent.

FISCAL NOTE

Marc Allen Connelly, Deputy General Counsel of the department, has determined that for each year of the first five years that the section will be in effect, there will not be fiscal implications to state or local governments as a result of implementing the section as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Connelly has determined that there will not be an adverse economic impact on small businesses or micro-businesses required to comply with the section as proposed. This was determined due to the fact that these guidelines do not require licensing and there are no enforcement provisions in the proposed rule or statute.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There will be no required costs to persons or facilities associated with implementing this rule as proposed. There will not be a negative impact on local employment.

PUBLIC BENEFIT

In addition, Mr. Connelly also has determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section. The criteria in the rule will protect adult stem cell donors by assuring them that the facilities where they choose to donate must meet identifiable criteria in order to operate as autologous adult stem cell banks.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Mr. Marc Allen Connelly, Department of State Health Services, Mail Code 1919, P. O. Box 14937, Austin, Texas 78714-9347 or by email at marc.connelly@dshs.state.tx.us, and please address the subject line to state “Comments for Adult Stem Cell Banks.” Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The new section is authorized by Health and Safety Code, §1003.001; and by Government Code, §531.0055 and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The new section affects Government Code, Chapter 531; and Health and Safety Code, Chapters 1001 and 1003.

Legend: (Proposed New Rules)
Regular Print = Proposed New Language

Subchapter V. Autologous Adult Stem Cell Banks.

§1.451. Purpose and Eligibility Criteria.

- (a) This section implements Title 12, Health and Safety Code, Chapter 1003.
- (b) Autologous Adult Stem Cells are stem cells taken from bone marrow, adipose tissue, or blood of a person to be transplanted into that same person.
- (c) Autologous Adult Stem Cell Bank is any facility that stores autologous adult stem cells for use in treatment or research.
- (d) An entity should apply the following criteria when establishing or operating an autologous adult stem cell bank in this state.
- (e) The governing body:
 - (1) shall be responsible for the organization, management, control, staffing, and operation of the facility;
 - (2) shall be formally organized in accordance with a written constitution and bylaws, which clearly set forth the organizational structure and responsibilities; and
 - (3) shall adopt, be responsible for, and ensure that operating and ethics policies and procedures are implemented and enforced.
- (f) The facility shall use current scientific standards for the collection, storage, manipulation and use of adult stem cells.
- (g) The facility shall ensure that services are provided in a safe and effective manner in compliance with all applicable state and federal laws and regulations.
- (h) The facility shall adopt and implement an effective, ongoing, quality assessment and performance improvement program to monitor and evaluate the collection, storage, manipulation and use of adult stem cells.
- (i) An autologous adult stem cell bank operating in this state shall file, on a department form, the following information:
 - (1) the bank's physical and mailing address and other contact information as specified;
 - (2) the owner, principle and/or supervising physician.

(j) The information may appear on the department's public web site. The information is not an endorsement by the department and may not be used in advertising by the stem cell bank, its parent or agent.